

REMARKS

The Examiner is thanked for the due consideration given the application. This Amendment is being filed concurrent with a Request for Continued Examination.

Claims 1-5 and 8-22 are pending in the application. Claim 1 has been amended.

No new matter is believed to be added to the application by this amendment.

Art Rejections

Claims 1, 2, 11 and 12 have been rejected under 35 USC §102(a) as being anticipated by KOIKE (WO 03/005907, relying upon by U.S. Publication 2004/0243165).

Claims 4, 5, 8, 10, 15 and 16 have been rejected under 35 USC §103(a) as being unpatentable over MARSHALL (U.S. Patent 5,487,748) in view of KOIKE.

Claims 3, 9, 13, 14 and 17-2 have been rejected under 35 USC §103(a) as being unpatentable over KOIKE or MARSHALL in view of KOIKE, and further in view of HAYNES (U.S. Patent 3,165,220).

These rejections are respectfully traversed.

The present invention pertains to a blood sampling device that is illustrated, by way of example, in Figures 5 and 6 of the application, which are reproduced below.

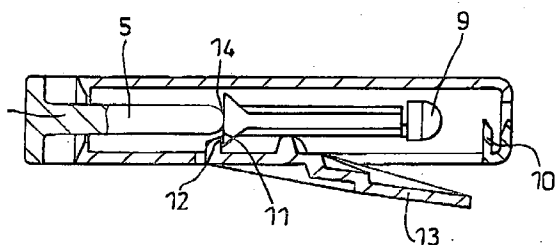


Fig. 5

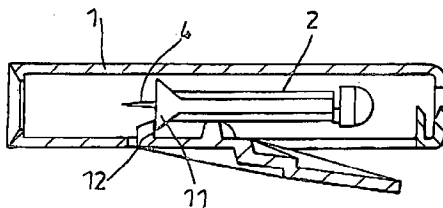


Fig. 6

In the present invention, the cap 5 is releasably attached to the lancet 2 adjacent the needle 4 and extends from its attachment to the lancet to pass through an opening in the housing of the device, the cap 5 and housing 1 cooperating so that the cap 5 holds the lancet 2 against movement relative to the housing 1.

Among the important features of the present invention are the following functions:

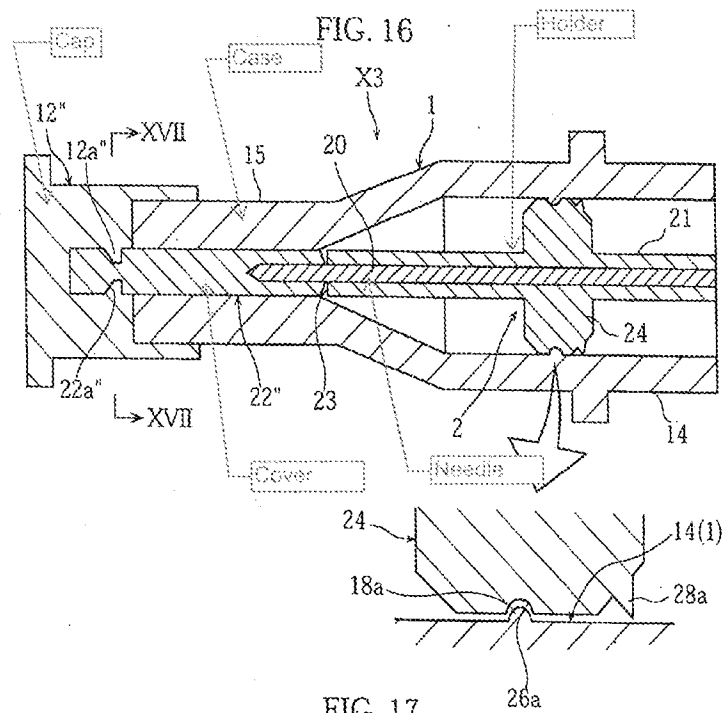
- Maintains sterility of the lancet needle.
- Holds the lancet needle against movement.
- Prevents inadvertent firing of the lancet.
- Reacts to load of the spring so that any trigger mechanism is not loaded until shortly before firing, thereby

avoiding the problem of 'plastic creep' that would arise if the trigger mechanism were subject to prolonged loading.

These functions are better reflected in claim 1, which has been instantly amended to recite "a housing," "a spring urging the lancet for movement in a forward direction towards an opening at one end of the housing," and "the cap initially holds the lancet against forward movement relative to the housing under influence of said spring." These amendments are supported by the drawing figures and the disclosure at paragraphs [0011] and [0012] of corresponding publication 2006/0129172.

The Official Action particularly points out the lancet illustrated in Figure 16 of KOIKE, an annotated version of which is reproduced below.

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Also note Figures 18(b) and 18(c) of KOIKE, which are reproduced below.

FIG. 18B

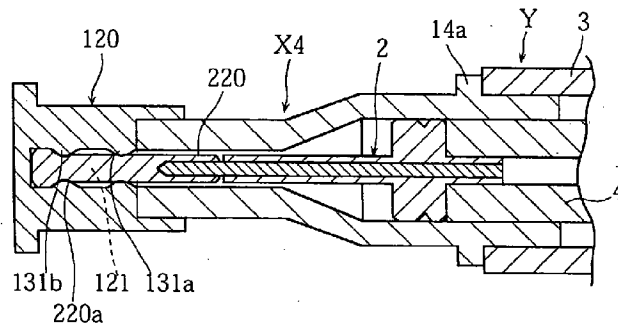
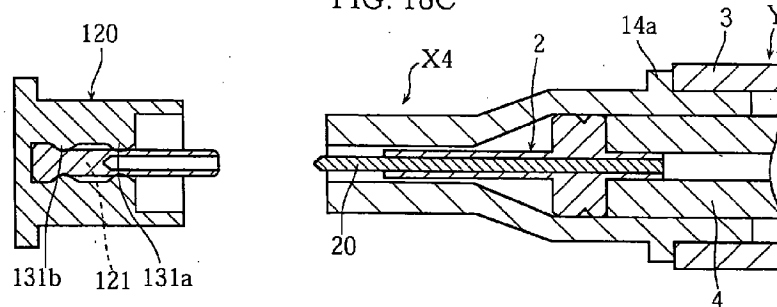


FIG. 18C



In the present invention an important point is what is meant by the cap holding the lancet against movement, and the applicant had interpreted this to mean that the cap held the lancet against forward and rearward movement, although the primary concern is holding the lancet against forward movement.

It would appear that the Official Action takes the view that this phrase is broad enough to cover the arrangement of Figure 16 of Koike et al., where the cap/stem would function to hold the lancet against rearward movement by a simple blocking action, but not against forward movement. Rather than being limited to the more restricted interpretation whereby movement in

either sense is prevented, claim 1 now makes explicit the feature that the device includes a spring urging the lancet forwardly and that the cap holds the lancet against forward movement, under the influence of the spring.

Applicant believes that this clearly distinguishes from KOIKE, because even if the cap/stem of KOIKE are considered to have the required locating member and cooperating feature (which applicant does not concede), it is clear that this arrangement of the cap/stem in Figure 16 of KOIKE does not prevent forward movement of the lancet and certainly not against the force of the drive spring.

The Office appears to argue that the terminology of the claim "*at least one locating member fitting into at least one cooperating feature of the outer walls of the housing*" can be read as covering the hollow cylindrical forward end of the housing of Koike et al., sliding into the annular recess defined between the stem 22'' and the skirt of the cap 12'' in plug fashion. This does not meet the requirement of fitting "*into*" because the claim requires a locating member on the cap to fit into at least one cooperating feature of the outer walls of the housing. There is no such member on the cap fitting into a feature in the housing outer wall. Furthermore, the claim requires the cap to be twistable to release the locating member from the cooperating feature and again, there is no such release action.

As has been noted, these unique features assure the following functions:

- Maintains sterility of the lancet needle.
- Holds the lancet needle against movement.
- Prevents inadvertent firing of the lancet.
- Reacts to load of the spring so that any trigger mechanism is not loaded until shortly before firing, thereby avoiding the problem of 'plastic creep' that would arise if the trigger mechanism were subject to prolonged loading.

These functions are unexpected in light of KOIKE.

With particular reference to independent claim 11 of the present invention, at page 7 the Office Action again relies upon Figure 16 of KOIKE. However, the disadvantages of Figure 16 equally apply to independent claim 11.

Additionally distinctions of the present invention over KOIKE (and MARSHALL) have been made of record in the application which, for brevity, are not repeated here.

Turning to MARSHALL, this does not add anything of significance. In particular, the cap does not engage releasably with the housing to hold the spring in the compressed position. Indeed, the design philosophy is somewhat different because in MARSHALL it is intended that the device is supplied to the user in the configuration shown in Figure 1 (reproduced below), namely with the spring in its relaxed position, with the user then

cocking the device and compressing the spring immediately prior to use.

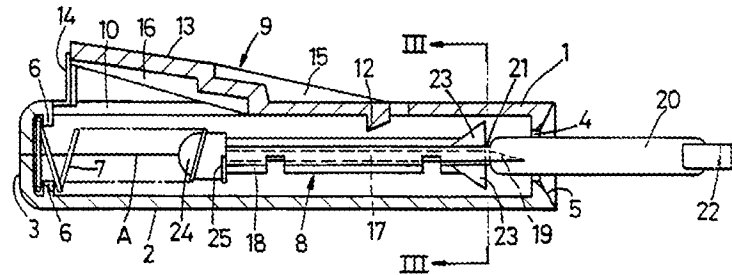


Fig. 1

In the present invention, of course, the device is intended to be supplied to the user ready-cocked. Even if MARSHALL were combined with KOIKE, the resulting combination would still be deficient because it would not show an arrangement in which the lancet was prevented from forward movement by the cap.

It should be reiterated that even if KOIKE is deemed to have the locating and cooperating features, there is no suggestion whatsoever in KOIKE that this arrangement would prevent forward movement of the lancet. Indeed, it will be seen from Figure 16 of KOIKE, that the lancet is initially held against movement by projections 18a on the inner cylindrical surface of the housing being received in an annular groove 26a on the lancet body.

Furthermore, the "lancet" shown in Figure 16 of KOIKE is actually a disposable unit intended to be fitted into a

lancing apparatus which contains the energy source for delivering an impact to the lancet to cause it to puncture the skin in use. Some care needs to be taken here because as seen for example in Figures 10(a) to 10(c), the "lancet" is pushed rearwardly into the lancing apparatus whereupon the lancet abuts a movement member 4. However, no suggestion can be found that the movable member 4 is spring loaded.

Referring back to MARSHALL, it will of course be appreciated that, in order to be capable of operating, the cap has to move, with the lancet, rearwardly relative to the housing to cock the spring, otherwise the device cannot operate. This would clearly teach away from combining the feature of a rearward restraint in KOIKE with the device of MARSHALL which clearly requires rearward movement of the lancet to cock it.

With particular reference to independent claim 15 of the present invention, at page 9 lines 5-7 the Office Action argues that the cap of MARSHALL is *"adapted to hold the lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of said trigger-releasable latch until said cap is detached from the lancet."*

In response, firstly, the cap of Marshall et al is not adapted to hold the lancet in any particular position. Certainly it is not adapted to hold the lancet latch surface spaced rearwardly from the latch surface of the trigger-releasable latch. Again, this is an important feature of the present

invention because it isolates the trigger mechanism from the force of the drive spring and prevents the problems associated with plastic creep. Clearly, if the two latches are spaced, there can be no forced transmission between the two. Of course, at a simplistic level the cap could be used by manual application to locate the lancet in such a position, but clearly the claim requires this to be a result of the engagement of the cap and the housing.

With particular reference to independent claim 11 of the present invention, at page 7 the Office Action again relies upon Figure 16 of KOIKE. However, the disadvantages of Figure 16 equally apply to independent claim 11.

Turning now to HAYNES, this discloses a tamper proof container and relates to a cap for closing a container. There is no teaching of an arrangement for a device in which the cap fulfils any other function than closing the neck and certainly not an arrangement where the cap extends through the neck of the housing to interact with a mechanism inside the housing to prevent its operation. It would thus not have been obvious to combine the teachings of KOIKE or MARSHALL with HAYNES.

As a result, the applied art neither anticipates the present invention nor renders the present invention *prima facie* unpatentable.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

CONCLUSION

Having addressed all the outstanding issues, the amendment is believed to be fully responsive. In view of the above, it is respectfully submitted that the application is in condition for allowance and notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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